K022961

RtDosePlan
File: rtksum.doc

JAN 3 1 2003

510(k) Summary

RtDosePlan is a radiation therapy external beam treatment planning program that supports treatment planning for x-rays only. The following functions are included:

1. Provide means to read in CT scans and form a patient model.
2. Provide means to define a skin boundary.
3. Provide means to convert CT numbers to physical density.
4. Provide means to define a plan that consists of one or more treatment beams.
5. Provide means to define a treatment beam.
6. Provide means to locate isocenter of the treatment beam within the patient model.
7. Provide means to set the gantry, collimator, and couch angles, and to specify a gantry arc rotation.
8. Provide means to specify a wedge.
9. Provide means to shape a field with a multi-leaf collimator.
10. Provide means to shape a field with auxiliary blocking (cerrobend).
11. Provide means to fit a poly-energetic pencil beam algorithm for the purpose of computing the dose.
12. Provide means to compute the dose to the patient model from the specified treatment beams.
13. Provide means to display the dose on 2d planes in the patient model and 3d room views.
14. Provide means to specify a dose prescription and calculate monitor units for each treatment beam.
15. Provide means to outline regions of interest.
16. Provide means to fuse other image sets and transfer outlines and points from the other image set.
17. Provide means to compute and display dose volume histograms.

Document Approved by: Wendel Dean Renner Wendel D. Renner
Title: President Date: Sept 4, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2003

Mr. Wendel Dean Renner
President
Math Resolutions, LLC
5975 Gales Lane
COLUMBIA MD 21045

Re: K022961
Trade/Device Name: RtDosePlan
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: October 31, 2002
Received: November 4, 2002

Dear Mr. Renner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

RtDosePlan
File: rtinduse.doc

510(k) Number: K022961

Device Name: RtDosePlan

Indications for Use:

This product is to be used by radiation therapy oncologist, dosimetrist, and radiation therapy physicist, to plan the treatment with x-rays for patients undergoing radiation therapy for stationary and gantry arc beams. Support is included for field shaping with multi-leaf collimators and auxiliary blocking, and the use of wedges. Electron therapy and intensity modulated radiation therapy is not included in this product.

Document Approved by: Wendel Dean Renner
Title: President
Wendel D. Renner
Date: Sept 4, 2002

NS / Prescription Device

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022961